



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,898	07/05/2001	Harm M. Deckers	034547-0104	3117

22428 7590 09/26/2003

FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

PAK, YONG D

ART UNIT	PAPER NUMBER
----------	--------------

1652

DATE MAILED: 09/26/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/897,898

Applicant(s)

DECKERS ET AL.

Examiner

Yong D Pak

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on July 11.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-18 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-18 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The amendment filed on July 11, 2003, canceling claims 25-28, has been entered.

Claims 14-18 and 29 are pending.

The rejection of claims 14-18 and 29 under 35 USC 103 has been withdrawn.

Priority

As previously stated, Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The second application must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the second application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ 2d 1077 (Fed. Cir. 1994).

The parent application, 09/577,147, does not disclose a method of preparing an emulsion formulation comprising a thioredoxin or thioredoxin reductase, which is claimed in the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14-15, 18 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCoy et al. in view of Loer et al.

McCoy et al. (U.S. Patent No. 5,646,016 – form PTO-892) teach a fusion molecule comprising a DNA sequence encoding a thioredoxin protein fused to DNA encoding a protein of interest. McCoy et al. teach that this fusion construct is advantageous because the thioredoxin facilitates the production of heterologous proteins (Columns 2-3).

The difference between the reference of McCoy et al. and the instant invention is that the reference of McCoy et al. does not teach a method of emulsifying the formulation comprising a fusion protein having a thioredoxin or thioredoxin reductase and an oil body protein.

Loer et al. (form PTO-892) teach DNA encoding an oil body protein, oleosin. Loer et al. also teach how to formulate oil body proteins into an emulsion (Page 994).

In the state of the art, methods of preparing products by forming emulsions are well known and practiced in the art. For example, U.S. Patent No. 5,683,740 (form PTO-1449) teach how to prepare oil bodies by washing and forming emulsions and ultimately concentrating the emulsion (Column 2).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made make a fusion protein comprising a thioredoxin gene and an oleosin gene and used the fused protein to make emulsions comprising the oil body. The motivation of making such fusion protein is to increased the efficiency of the production of the protein. One of ordinary skill in the art would have had a reasonable expectation of success since fusion proteins are made routinely in the art and preparation of oil bodies by forming emulsions are also practiced routinely in the art.

Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCoy et al. in view of Loer et al. as applied to claims 14-15, 18 and 29 above, and further in view of Hildebrand et al.

The references of McCoy et al. and Loer et al. in combination teach a method of making a fusion protein comprising a thioreodixn and an oil body, as discussed above.

The difference between the combined references and the instant invention is that the combined teachings of McCoy et al. and Loer et al. do not teach the method using a safflower cell for the expression of the fusion protein.

Hildebrand et al. (EP 0 550 162 A1 – form PTO-892) teach a method of expressing heterologous proteins in safflower cells (page 4).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to express the fusion protein in safflower cells. The motivation of expressing the fusion protein in safflower cells is to express the oil body protein in an oil-bearing crop. One of ordinary skill in the art would have had a reasonable expectation of success since expression of fusion proteins in plant cells such as safflower cells are performed routinely in the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Application/Control Number: 09/897,898


Page 6

Art Unit: 1652

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

September 23, 2003



PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600